

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



FEE

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

~~DOCUMENT CONTAINS CONFIDENTIAL INFORMATION~~

DP BARCODE No.: D428667; **FILE SYMBOL No.:** 2724-IUE; **PRODUCT NAME:** RF2236 CDSO-N1 for Dogs; **DECISION No.:** 506636; **PC Code(s):** 129032, 057001, 067501, 128965; **ACTION CODE:** R301; **FOOD Use:** No

DATE OUT: August 25, 2015

SUBJECT: End Use Product Chemistry Review
Product Name: RF2236 CDSO-N1 for Dogs

FROM: Shyam Mathur, Ph.D
Product Chemistry Team Leader
CITAB/RD (7505P)

S Mathur
8/25/15
JCR

TO: Elizabeth Fertich / Jennifer Urbanski, RM 04
I-V Branch 1 / RD (7505P)

Company Name: Wellmark International
Formulation Type: Insecticide

INTRODUCTION:

The registrant has submitted an application to register a new end use product RF2236 CDSO-N1 for Dogs which contains four active ingredients, namely, Nylar, Ethofenprox, MGK-264 and PBO. The registrant has submitted a CSF for basic formulation dated July 02, 2015 and the product label. In support of the basic CSF, the registrant has submitted 830 series group A with MRID Nos. 49668001, 49668002 and cited group B data with MRID No. 48405601. The registrant has claimed that the proposed product is substantially similar to the cited product with Reg. No. 2596-168. CITAB has been asked to determine the acceptability of the proposed basic CSF and the supporting product chemistry data and also determine similarity to the cited product.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Etufenprox (55.0%), PBO (10.0%), MGK-264 (1.0%) and Nylar (0.50%)
2. Has the registrant claimed substantial similarity to a registered product?

[X] Yes; [] No; [] NA; if yes, give the registration number of the cited product.

Reg. No. 2596-168

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3. All of the source materials of the active ingredient are derived from registered sources: ☒ Yes ☐ No
4. All inert ingredients have been screened by IIAB and found to be approved for the proposed labeled Uses: ☒ Yes; ☐ No

5. Confidential Statement of Formula(s):

☒ Proposed Basic - Dated: 07-02-2015; Re-submitted – Dated:

☐ Proposed Alternate CSF – All Dated: ; Re-submitted – All Dated:

Alternate CSF(s) complies with 40CFR§152.43: ☐ Yes; ☐ No; ☒ NA

6. Product label

- a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2).

☒ Yes; ☐ No; if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)

☒ Yes; ☐ No; if not, explain below:

Metallic equivalent: ☐ Yes ☒ NA
Soluble arsenic: ☐ Yes ☒ NA
Isomeric ratios: ☐ Yes ☒ NA
Acid Equivalent: ☐ Yes ☒ NA;

- b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes ☐ No ☒ NA
Methanol at > 4%: ☐ Yes ☐ No ☒ NA
Sodium nitrate/Sodium Nitrite ☐ Yes ☐ No ☒ NA

- c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for flammability, explosive potential or electric insulator breakdown?

☐ Yes; ☒ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes; ☐ No; ☒ NA; if not, explain below

- d. Label requires an additional Storage and Disposal statement:

☐ Yes; ☒ No; if yes explain below:

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7. Group A: Product Chemistry Data

CITAB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		CITAB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		N	49668002
830.1600	Description of materials used to produce the product		X		A	49668002
830.1650	Description of formulation process		X		A	49668002
830.1670	Discussion on the formation of impurities		X		A	49668002
830.1700	Preliminary analysis				NA	
830.1750	Certified limits (158.350)	Standard certified limits	X		N	Basic CSF dated 07-02-2015
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method		cited		A	49668001

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable.

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8. Group B: Cited from Reg. No. 2596-168

Guideline No.	Study Title	Value or Qualitative Description	CITAB's Assessment of Data	MRID Nos. cited
830.6303	Physical State	Liquid @ 22.8°C	N	48405601
830.6314	Oxidation/reduction	Does not contain any oxidizing or reducing agents	N	48405601
830.6315	Flammability	>210 °F	N	48405601
830.6316	Explosibility	Not potentially explosive	N	48405601
830.6317	Storage stability	No data submitted. Study in progress	N	Data matrix dated 7-02-2015 48405601
830.6320	Corrosion characteristics	No study submitted. Study in progress	N	Data matrix dated 7-02-2015 48405601
830.7000	pH	Not dispersible in water	N	48405601
830.7100	Viscosity	<100 cps @ 20°C	N	48405601
830.7300	Density	8.53 lbs/gal (1.022 g/ml) @20.0°C	N	48405601

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CONCLUSIONS:

The CITAB has reviewed the product chemistry data submitted for the proposed end-use product and has concluded that:

1. Since the proposed product was determined not be identical to the cited product, the cited group B data will not support the proposed CSF for basic formulation (dated 07-02-2015) and is, therefore, not acceptable. The proposed CSF may be revised if needed. The registrant is recommended to re-submit the basic CSF incorporating the determined physical-chemical chemical properties generated on the proposed product.
2. The data submitted corresponding to guidelines 830.1550 (product identity & composition), 830.1600 (description of materials used to produce product), 830.1650 (description of formulation process), 830.1670 (description of formation of impurities), and 830.1750 (certified limits) and cited data for 830.1800 (enforcement analytical method) are acceptable.
3. Since the proposed product and the cited product are not identical in chemical composition, the product chemistry data cited corresponding to guidelines 830.6302 (color), 830.6303 (physical state), 830.6304 (odor), 830.6314 (oxidation/reduction), 830.6315 (flammability), 830.6316 (explodability), 830.6317 (storage stability), 830.6320 (corrosion characteristics), 830.7000 (pH), 830.7100 (viscosity) and 830.7300 (density) are not acceptable. The registrant must generate group B product chemistry data for the proposed and the results must be submitted to the Agency.
4. The proposed product with FSN: 2724-IUE was determined not to be identical in chemical composition to the cited product with Reg. No. 2596-168.